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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,851	05/28/2002	Horst Rapp	HMN 2 0021	8437
27885	7590	12/10/2008	EXAMINER	
FAY SHARPE LLP 1100 SUPERIOR AVENUE, SEVENTH FLOOR CLEVELAND, OH 44114			CHONG, YONG SOO	
			ART UNIT	PAPER NUMBER
			1617	
			MAIL DATE	DELIVERY MODE
			12/10/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/031,851	RAPP ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	YONG S. CHONG	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 September 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3,6-21 and 34-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3,6-21 and 34-45 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/20/08</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____.                         |

## DETAILED ACTION

### ***Status of the Application***

This Office Action is in response to applicant's remarks filed on 9/18/2008.

Claims 2, 4-5, 22-33 have been cancelled. Claims 34-45 are new. Claims 1, 3, 6-21, 34-45 are pending. Applicant's election **without traverse** of the restriction requirement in the reply is acknowledged. The requirement is deemed proper and is therefore made FINAL. Claims 1, 3, 6-21, 34-45 are examined herein insofar as they read on the elected invention and species.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 6-21, 34-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandevelde et al. (WO 91/07876) in view of Berger (US Patent 4,574,084).

Vandevelde et al. discloses that tosylchloramide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-8 and claims 1-28). Vandevelde et al. discloses the pharmaceutical compositions of tosylchloramide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-13 at page 9-20).

Generally, mere optimization of ranges will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimal or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); “The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.” *In re Peterson*, 315 F. 3d at 1330, 65 USPQ 2d at 1382; It has been held that it is within the skills in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 1980) MPEP 2114.04

Vandevelde et al. does not expressly disclose the employment of tosylchloramide(s), in methods of the particular skin diseases herein.

Berger discloses the general teaching that common inflammatory skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi. Furthermore, these skin diseases can be effectively treated with biocidal compositions that are used for disinfection (col. 7, line 61 to col. 8, line 8).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes because: (1) Vandevelde et al. teach an antimicrobial pharmaceutical composition comprising tosylchloramide(s) and their salts for treating skin diseases; (2) Berger teaches that common skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi; and (3) Berger also give the general teaching that such skin diseases can be treated with biocidal compositions that are used for disinfection. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating skin diseases such as psoriasis and herpes with an antimicrobial composition comprising tosylchloramide(s) as disclosed by Vandevelde et al. because of the beneficial therapeutic effects of tosylchloramide(s) on killing and destroying harmful microorganisms that cause such skin diseases.

***Response to Arguments***

Applicant argues that Vandevelde is directed to disinfecting inanimate objects, which are contaminated with the HIV virus. The active ingredients are for disinfection matters only. There is absolutely no indication in Vandevelde that chloramine-T is used in a medicament or pharmaceutical composition or suitable for the treatment of skin diseases, much less herpes simplex virae.

This is not persuasive because Vandevelde clearly teaches the use of the chlorinated organic active agents, including chloramine-T, as a therapeutic composition which acts against viruses (abstract). Nonetheless, the mere mention that chloramine-T acts against viruses on inanimate objects provides sufficient motivation to administer a composition comprising chloramine-T as a medicament or a pharmaceutical composition because one of ordinary skill in the art would have had a reasonable expectation of success in treating a viral disease. Applicant is reminded that the standard of obviousness is not absolute but a reasonable expectation of success.

Applicant also argues against the combination of the Vandevelde and Berger references because Berger teaches the use of an aqueous chlorite solution stabilized with a peroxide compound, whereas Vandevelde employs totally distinct biocidal compounds.

This is not persuasive because the Berger reference was merely used to teach the nexus between skin diseases and biocidal compositions that are used for disinfection, since common inflammatory skin diseases, such as psoriasis and herpes,

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and caused by bacteria, viruses, and fungi. In this manner, the Berger reference was not relied on for any teaching of therapeutically active agents.

Claims 1, 3, 6-21, 34-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harwardt et al. (DE 41 37 544) in view of Berger (US Patent 4,574,084).

Harwardt et al. discloses that tosylchloramide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-4 and claims 1-7). Harwardt et al. discloses the pharmaceutical compositions of tosylchloramide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-5 at page 3-4).

Harwardt et al. does not expressly disclose the employment of tosylchloramide(s) in methods of the particular skin diseases herein.

Berger teach as discussed above.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes.

One having ordinary skill in the art at the time the invention was made would

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have been motivated to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes because: (1) Harwardt et al. teach an antimicrobial pharmaceutical composition comprising tosylchloramide(s) and their salts for treating skin diseases; (2) Berger teaches that common skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi; and (3) Berger also give the general teaching that such skin diseases can be treated with biocidal compositions that are used for disinfection. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating skin diseases such as psoriasis and herpes with an antimicrobial composition comprising tosylchloramide(s) as disclosed by Harwardt et al. because of the beneficial therapeutic effects of tosylchloramide(s) on killing and destroying harmful microorganisms that cause such skin diseases.

### ***Response to Arguments***

Applicant argues that Harwardt is not directed to treating skin diseases caused by herpes simplex virae, since the reference only discloses a combination of active ingredients for antiseptic and disinfection purposes. Applicant continues to argue that Hardwardt teaches that single ingredients, for example chloramine-T alone, are not suited for antiseptic or disinfection purposes. Applicant also argues nonobviousness in combining Hardwardt with the Berger reference since peroxide compounds as active ingredients.

This is not persuasive because Applicant has again attacked each reference individually for lacking the teaching that is provided for in the other reference. Although Harwardt does not teach treating skin diseases, the Berger reference teaches the nexus between skin diseases and disinfecting active ingredients. Specifically, the Berger reference teaches that common inflammatory skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi, which can be effectively treated with biocidal compositions that are used for disinfection. Further, there is nothing in the Harwardt reference that teaches that chloramine-T alone is not suited for antiseptic or disinfection purposes. Furthermore, the argument regarding nonobviousness in combining the Harwardt and Berger references does not make sense since the Berger reference was not used for teaching any active ingredients and also since the claims use the open transitional phrase "comprising," so as to not preclude the inclusion of other active ingredients in the pharmaceutical composition.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S Chong/  
Examiner, Art Unit 1617

YSC